484 Assessed for Eligibility

433 Excluded:
  103 Fracture extended into the joint
  99 Non-intramedullary nail operative treatment or conservative treatment
  59 Less than 18 years of age
  47 Patient could not comply with protocol
  32 Concomitant injury which was likely to impair function for as long as or longer than the subject’s tibial fracture
  20 Problems anticipated with follow-up
  19 Treating surgeon refused to randomize patient
  15 Approached for consent >14 days from operative treatment
  11 Patient already in a competing study
  9 Pathological fracture
  6 Bilateral tibial fractures
  6 Circumferential, open wound that precludes placement of ultrasound at the fracture site
  4 Grade IIIb or IIIc fracture
  3 Surgical delay of >14 days

51 Randomized*

28 Assigned to Control (Sham LIPUS)
  6 Lost prior to 1 year
  22 Available for Analysis at 1 year

23 Assigned to Treatment (Active LIPUS)
  2 Lost prior to 1 year
  21 Available for Analysis at 1 year

* There was one stratification error, when a patient with an open fracture received an ultrasound unit designated for the next patient with a closed fracture